Long-Term Safety of Magnetic Resonance Guided Focused Ultrasound in Movement Disorders - A Comprehensive Review of Outcomes

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Magnetic resonance–guided focused ultrasound (MRgFUS) is a CE-approved, non-invasive treatment for movement disorders as Parkinson's disease, Essential Tremor, and for neuropathic pain. Since 2012, over 25,000 procedures have been performed globally, with growing adoption across Europe. Clinical trials show promising safety and efficacy; ongoing real-world evaluation is essential to fully understand long-term outcomes.

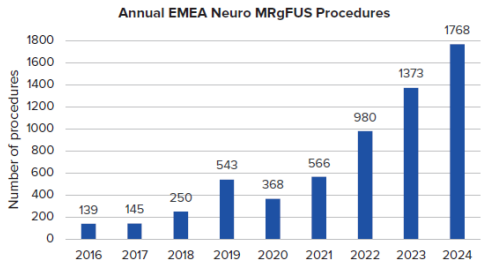

Figure 1. Adoption of magnetic resonance-guided focused ultrasound (MRgFUS) has been increasing steadily since its introd tion in 2016

Essential Tremor (ET)

Pivotal Trials on Unilateral MRgFUS thalamotomy in moderate-to-severe ET reduced tremor by 47% at 3 months vs. 0.1% with sham ($p<0.001$) [2], with mostly mild/moderate non-transient AEs such as paresthesia and imbalance; no new AEs were reported over 5 years (Table 1) [2,11,12]. Bilateral treatment (n=51) showed a 66% CRST improvement, with similar AEs including dysarthria and taste disturbance (Table 2) [5]. A literature review of 16 studies (n=1214) confirmed comparable safety, with mild transient AEs (e.g., headache, nausea) and mild-to-moderate gait/sensory disturbances (Table 3) [13–28].

Parkinson's Disease (PD)

Pivotal trials and literature on four MRgFUS targets (GPi, VIM, STN, PTT) reported mostly mild AEs, including gait issues, speech disturbances, and paresthesias (Table 4) [3,4,6–10].

Post-Marketing Surveillance

Among 21,922 real-world procedures (2017–2024), 256 AEs (1.2%) were reported, mainly gait disturbances, imbalance, and paresthesia, with no unexpected safety signals (Table 3).

User Survey

In 2024, 56 users from 29 centers across 11 EMEA countries rated MRgFUS safety. The average satisfaction score was 4.1 out of 5, with 85% rating it as very good or excellent.

Conclusions

Real-world data confirm the safety of MRgFUS for ET and PD, consistent with pivotal trials and literature. No trend in unexpected AEs was observed. These findings support MRgFUS as a safe, advanced therapy for movement disorders.

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Methods

Long-term safety findings from real-world sources (published literature, post-marketing surveillance data, customer survey) were collated and compared with safety findings from the pivotal trials of unilateral and staged bilateral MRgFUS thalamotomy in patients with ET. In addition, a literature review was conducted to identify published results on MRgFUS treatment in PD.

Table 1. Non-transient MRgFUS thalamotomy-related adverse events in the pivotal trial and long-term follow-up of unilateral treatment in patients with essential tremor [2,11,12]

Adverse event*		1 week (n = 56)	3 months (n = 56)	1 year (n = 56)	3 years (n = 52)§	5 years (n = 40)§
Paresthesia or numbness, any region		30%	25%	14%	21%	20%
Gait disturbance	Ataxia‡	18%	4%	4%	2%	5%
	‡Unbalanced†	14%	13%	5%	12%	15%
	‡Unsteady†				4%	5%
Taste disturbance		5%	4%	4%	2%	5%
Dysmetria, limb		13%	9%	4%	2%	5%
Weakness		4%	4%	2%	4%	5%
Dysarthria / Dysphagia		4%	4%	0%	2%	0%
Headache		7%	4%	0%	-	3%
Fatigue		5%	2%	0%	2%	-

* Patients may have had more than 1 adverse event.
§ Data were unified for the treatment arm (n = 56), crossover arm (n = 19), and 2 patients were assigned to treatment in which the procedure was repeated (n = 2). Percentages are based on the number of patients observed at 3 years (n = 52) and 5 years (n = 40), not on the total number of procedures performed (n = 77).
‡ Noted objectively on examination.
† Reported subjectively by patient or examiner.

Table 2. Non-transient (>72 hours) MRgFUS thalamotomy-related adverse events in a single-arm trial of staged bilateral treatment in patients with essential tremor [5]

Adverse event*	Total (n = 51)	1 month (n = 51)	3 months (n=50)	6 months (n=50)	12 months (n=47)
Paresthesia or numbness, any region	33%	22%	18%	16%	17%
Dysarthria	29%	19%	16%	14%	15%
Gait disturbance	10%	6%	4%	2%	2%
Ataxia	24%	18%	16%	14%	13%
Unsteadiness/imbalance	20%	10%	6%	0%	0%
Dysgeusia	14%	14%	14%	6%	6%
Hypogeusia	8%	8%	8%	8%	6%
Dysphagia	8%	8%	6%	6%	6%
Dysmetria	4%	2%	2%	2%	0%
Fatigue	4%	2%	2%	0%	0%

* Table includes >2% incidences. Patients may have had more than 1 adverse event.
All events were mild except for 5 moderate events (dysarthria and headache – 1 month, imbalance – 6 months, dysgeusia and dysphagia – ongoing 12 months)

Table 3. Adverse events reported after MRgFUS thalamotomy in the pivotal clinical trial in unilateral treatment of essential tremor [2], trial of bilateral treatment [5], other comparable clinical trials in essential tremor [13–28], and during postmarketing surveillance

Adverse event (%)	Unilateral treatment (pivotal trial) (N=56)	Staged bilateral treatment (N=51)	Literature review (N=10–270)	Postmarketing surveillance 2017–2024 (N=21,920 procedures)
Ataxia	4	16	13 (3–24)	0.29
Gait disturbance	13	4	16 (2–26)	
Unbalanced		6	24 (5–29)	0.15
Paresthesia/numbness	25	18	19 (2–30)	0.23
Dysmetria	9	2	12 (9–14)	0.02
Dysarthria	4	16	5 (2–8)	0.10
Dysgeusia	4	14	9 (4–11)	0.06
Weakness	4	2	5 (1–7)	0.21
Headache	4	0	-	-
Dysphagia	2	6	5 (1–8)	-
Fatigue	2	2	2 (0–3)	-
Dystonia	-	-	-	0.01
Sensation of disequilibrium/dizziness	5	0	-	0.03
Face swelling	-	-	-	0.01
Hemiparesis	-	-	-	0.02
Skin redness	-	-	-	0.01
Insomnia/clumsiness/jumpiness	-	-	-	0.01
Other (thalamic pain, pneumocephalus, burn)	-	-	-	<0.01 each

Table 4. Most common treatment-related adverse events after unilateral MRgFUS thalamotomy for Parkinson's disease, by target area

Adverse event (%)	STN MRgFUS (N=10–27)ª [3,6–8]	GPi MRgFUS (N=68)ª [4]	VIM MRgFUS (N=26)ª [9]	PTT MRgFUS (N=47)ª [10]
Speech disturbance/dysarthria	10–56	3	5	15
Gait disturbance/ataxia	15–60	3	35	-
Dyskinesia	0–22	-	-	-
Dystonia/leg cramp	-	3	-	-
Weakness	8–19	-	20	-
Facial asymmetry	10–20	2	-	-
Dysmetria	7–8	-	5	-
Paresthesia	0–10	2	27–39	-
Hypoesthesia, scalp	-	-	-	2
Loss of taste	-	3	-	-
Weight gain	0–20	-	-	-
Somnolence/fatigue	4–10	-	-	-
Behavioral change/mood disorder	4–30	-	-	2

Adverse events during up to 12-months' follow-up after MRgFUS procedure (i.e. excluding transient intraprocedural events).
ª No adverse events were reported in control groups (sham procedure) comprising 13 [3], 24 [4], or 7 [9] patients.
ᵇ 15 patients received bilateral PTT.
GPi=globus pallidus; PTT=pallidothalamic tract; STN=subthalamic nucleus; VIM=ventral intermediate thalamus.